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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,330	09/12/2005	Gary N. Mills	31030/3:2 USA	6689

7590 11/06/2007

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EXAMINER	
SZMAL, BRIAN SCOTT	
ART UNIT	**PAPER NUMBER**
3736	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

CT

Office Action Summary	Application No.	Applicant(s)	
	10/549,330	MILLS ET AL.	
	Examiner	Art Unit	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 September 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/12/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 3-17 and 22-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Baura et al (6,561,986 B2).

Baura et al disclose a means for hemodynamic assessment and further disclose providing a first set of injection electrodes and a second set of measurement electrodes; positioning members of the first set of electrodes on the body to introduce electrical current flow through the tissue and thereby establish flow paths that define injection vectors along which electrical currents flow between two or more injection electrodes; positioning members of the second set of electrodes on the body to define measurement vectors relating to electrical voltages produced in response to the electrical currents flowing between the injection electrodes, the injection and measurement vectors defining an anatomical space of the tissue; deriving from each of different pairs of the injection and measurement vectors an electrical bio-impedance value that is characteristic of the electrical bio-impedance of a region of the anatomical space; analyzing the electrical bio-impedance values to detect a presence of a volume of fluid or change in a volume of fluid in the anatomical space; the electrical current flow

is introduced by a complex electrical current waveform and the analyzing of the electrical bio-impedance value includes chirp transform analysis or waveform analysis; the analyzing of the electrical bio-impedance values entails determining differences in the electrical bio-impedance values derived from the injection and measurement vectors; determining temporal changes in the electrical bio-impedance values derived from the injection and measurement vectors; the analyzing of the electrical bio-impedance values entails determining temporal changes in the electrical bio-impedance values derived from the injection and measurement vectors; each member of the first set includes a current source and a current sink, the current source and current sink being positioned at locations on the body such that electrical current flowing from a current source of one of the members flows into a current sink of another one of the members; each member of the first set includes multiple current sources and multiple current sinks, the current sources and current sinks being positioned at locations on the body such that electrical current flowing from a current source of one or electrical currents flowing from current sources of more than one of the members flow into one or more current sinks of another one of the members; the injection and measurement vectors define a nominal shape of the anatomical space in the presence of a nominal quantity of fluid, and in which the presence of other than the nominal quantity of fluid changes the anatomical space from its nominal shape; analyzing the electrical bio-impedance values to determine the extent of fluid volume in the mammalian tissue; the fluid includes blood, and further comprising analyzing the electrical bio-impedance values to determine whether the presence of a volume of blood indicates an

accumulation or a loss of blood; processor circuitry operatively connected to the injection current source and the sensor amplifier circuitry, the processor circuitry programmed with instructions to process signals representing the injection electrical currents and the produced voltages corresponding to different pairs of the injection and measurement vectors, to compute from each of different pairs of the injection and measurement vectors an electrical bio-impedance value that characterizes the electrical bio-impedance of the mammalian tissue in an anatomical space, and to analyze the electrical bio-impedance values to detect a presence of or a change in a volume of fluid in the anatomical space; memory stores operatively associated with the processor circuitry to store the computed electrical bio-impedance values, the memory stores being separable from the instrument and capable of retaining the computed electrical bio-impedance values upon separation from the instrument; an internal electrical power supply, thereby facilitating instrument portability; the sensor amplifier circuitry includes amplifier circuitry operating in a differential input mode and having a gain value suitable for electrocardiogram (ECG) signal acquisition, the amplifier circuitry operating in a differential input mode having an output, and in which selected ones of the multiple electrodes provide electrical voltages representing acquired ECG signals, multiple ones of the acquired ECG signals being operatively coupled to the amplifier circuitry operating in a differential input mode, and further comprising: pulse-generator pulse amplifier and detector circuitry to which an analog signal produced across two of the multiple electrodes is operatively coupled, the pulse-generator pulse amplifier and detector circuitry producing an output in response to characteristics of the analog signal

that represent signal characteristics of a pulse produced by a pulse generator operatively connected to the mammal; and the processor circuitry programmed with instructions to process signals corresponding to the outputs of the amplifier circuitry operating in the differential input mode and the pulse-generator pulse amplifier and detector circuitry to produce an electrocardiogram signal representation; the electrocardiogram signal representation produced includes a signal component that indicates a presence or an absence of a pulse-generator pulse; a housing connector to which a connection block module is releasably attachable for matable connection, the multiple electrodes connected by associated electrically conductive leads to the connection block module, and the connection block module including at least one of a battery, defibrillator discharge protection, or memory; an enclosure in which the instrument is contained, the enclosure further containing one or more equipment modules that form with the instrument an integrated system by common operational access to one or more of a display, power supply, memory, controls, or input/output connection; an enclosure in which the instrument is contained, the enclosure further containing a collection of one or more independently operating equipment modules; an input/output connection device that is operatively associated with the processor circuitry and is configured to receive information from and to export information to an external location; and the input/output device and the external location are operatively connected by a communication link of one of a wire line or a wireless medium type. See Figure 12; Column 19, lines 30-67; Column 20; and Column 21, lines 1-54.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baura et al (6,561,986 B2) as applied to claim 1 above, and further in view of Takehara et al (2002/0022787 A1) in view of Duong et al (6,740,518 B1).

Baura et al, as discussed above, disclose a means for hemodynamic assessment but fail to disclose the electrical current flow is introduced at multiple signal frequencies and the analyzing of the electrical bioimpedance value includes Fourier analysis and data reduction.

Takehara et al disclose a means for measuring body water concentration via multi-frequency bioimpedance measurements and further disclose the electrical current flow is introduced at multiple signal frequencies. See Paragraphs 0039-0046.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Baura et al to include the use of multi-frequency currents, as per the teachings of Takehara et al, since it would provide a means of more accurately determining any changes in the tissue impedance based on the increased applied current.

Baura et al and Takehara et al however fail to disclose analyzing the acquired data through the use of Fourier transform and data reduction.

Duong et al disclose a means for detecting analytes and further disclose analyzing the acquired data through the use of Fourier transform and data reduction. See Column 86, lines 48-51; and Column 89, lines 1-21.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Baura et al and Takehara et al to include the use of Fourier transform and data reduction, as per the teachings of Duong et al, since it is well known in the art to utilize data analysis methods such as Fourier transform and data reduction when dealing with acquired impedance measurements.

5. Claims 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baura et al (6,561,986 B2) as applied to claim 12 above, and further in view of Carter et al (5,674,264).

Baura et al, as discussed above, disclose a hemodynamic assessment means but fail to disclose electrode selector switch circuitry through which the multiple electrodes are operatively coupled to the injection current source and the sensor amplifier circuitry, the electrode selector switch circuitry responsive to command information delivered from the processor circuitry to select which ones of the multiple electrodes introduce the electrical current flow and which ones of the multiple electrodes define measurement vectors relating to the electrical voltages produced; the electrode selector switch circuitry is configured for independent selection of the multiple electrodes in response to the command information; the command information delivered to the electrode selector switch circuitry selects sets of the multiple electrodes to define multiple electrode assemblies, each of the multiple electrode assemblies including on a

common substrate a first electrode structure that introduces injection electrical current flow and a second electrode structure that defines a measurement vector relating to the electrical voltages produced; and each of the first and second electrode structures includes at least one electrode segment.

Carter et al disclose a feedback system to control electrode voltages and further disclose electrode selector switch circuitry through which the multiple electrodes are operatively coupled to the injection current source and the sensor amplifier circuitry, the electrode selector switch circuitry responsive to command information delivered from the processor circuitry to select which ones of the multiple electrodes introduce the electrical current flow and which ones of the multiple electrodes define measurement vectors relating to the electrical voltages produced; the electrode selector switch circuitry is configured for independent selection of the multiple electrodes in response to the command information; the command information delivered to the electrode selector switch circuitry selects sets of the multiple electrodes to define multiple electrode assemblies, each of the multiple electrode assemblies including on a common substrate a first electrode structure that introduces injection electrical current flow and a second electrode structure that defines a measurement vector relating to the electrical voltages produced; and each of the first and second electrode structures includes at least one electrode segment. See Column 3, lines 1-13; Column 5, lines 63-67; and Column 6, lines 1-4.

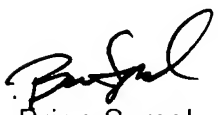
It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Baura et al to include the use of electrode

switch circuitry as per the teachings of Carter et al, since it would provide a means of controlling multiple electrodes while obtaining an optimum measurement from the body.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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